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Sponsor/company:	**sanofi-aventis**	**ClinialTrials.gov Identifier:**	**NCT00263055**
		Study Code:	**R_9262**
Generic drug name:	**Oxaliplatin**	**Date:**	**30-Aug-2007**

Title of the study:	Multicenter Asia Study in adjuvant treatment of Colon cancer with OxaliplaTin/5FU-LV (MASCOT) (R_9262)
Investigator(s):	Dr. Jiafu Ji, Department of Gastric and Intestinal Surgery, Beijing Cancer Hospital, Beijing, China Dr. Yingjiang Ye, Department of Gastric and Intestinal Surgery, People's Hospital of Beijing, Beijing, China Dr. Yingqiang Shi, Department of Gastric and Intestinal Surgery, Shanghai Cancer Hospital, Shanghai, China Dr. Desen Wan, Department of Gastric and Intestinal Surgery, Zhongshan Cancer Hospital, Guangzhou, China Dr. Sze Wai-Man & Dr. Yeung Mei-Wan Rebecca, Pamela Youde Nethersole Eastern Hospital, Hong Kong Dr. Fu Yiu-Tung, Queen Elizabeth Hospital, Hong Kong Dr. Young Suk, Park, Samsung Medical Center, Seoul, Korea Dr. Kyung Hae Jung, National Cancer Center, Gyeonggi-do, Korea Dr. Dong Bok Shin, GIL Medical Center, In-cheon, Korea Dr. Myung Ju Ahn, Hanyang Medical Center, Seoul, Korea Dr. Young Yiul Lee, Hanyang Medical Center, Seoul, Korea Dr. Po-Huang Lee, National Taiwan University Hospital, Taipei, Taiwan Dr. Tzu-Chi Hsu, Mackay Memorial Hospital, Taipei, Taiwan Dr. Hwei-Ming Wang, Veterans General Hospital, Taichung, Taiwan Dr. Cheng-Shyong Chang, Changhua Christian Hospital, Changhua, Taiwan Dr. Wei-Shou Hwang, Chi-Mei Foundation Hospital, Tainan, Taiwan Dr. Vorachai Ratanatharathorn, Ramathibodi Hospital, Mahidol University, Thailand

Study center(s):	China: 4 centers Hong Kong, China: 2 centers Korea: 4 centers Taiwan: 6 centers Thailand: 1 center		
Publications (reference):	N/A		
Study period: Date first patient enrolled: 13-Aug-2004 Date last patient completed: 05-Dec-2006		**Phase of development:** Phase IV	
Objectives:	To evaluate the safety and tolerability of FOLFOX4 regimen in the adjuvant treatment of colon cancer in Asian patients		
Methodology:	Multicenter, open-labeled, non-randomized, single arm		
Number of patients:	Planned: 160	Randomized: N/A	Treated: 162
Evaluated:	159	Safety: 159	
Diagnosis and criteria for inclusion:	Histologically proven stage Dukes « B2 » and « C » colon carcinoma with inferior pole of the tumor above the peritoneal refection; Having undergone complete resection of the primary tumor; Being entered in the study to start treatment within 7 weeks after surgery		
Investigational product:	• Oxaliplatin: 85 mg/m² in a 2 hour intravenous infusion, D1 • 5-FU: 2000 mg/m²/cycle (400 mg/m² bolus, D1 and D2, 600 mg/m² 22 hour continuous infusion, D1 and D2) • Leucovorin 200 mg/m², in a 2 hours intravenous infusion, D1 and D2		
Duration of treatment:: 24 weeks (2 weeks/cycle, 12 cycles)		**Duration of observation:** 1 year	
Reference therapy:	N/A		

Criteria for evaluation:	
Efficacy/Pharmacodynamics:	N/A
Safety and Tolerability:	• Occurrence of dose-limiting toxicity • Occurrence of one or more adverse event in a patient • Overall distribution of intensity of adverse events • Occurrence of particular adverse events and their intensities • Percent of patients completing study treatment • Percent of patients with grade 1, 2 and 3 neuropathy at 28 days, 6 months and 12 months after last chemotherapy administration. • Percent of intended dose delivered for 5-FU/LV and Oxaliplatin • Delays in scheduled dosing • Dose intensity, as expressed as the amount of 5-FU/LV and Oxaliplatin administered divided by the duration of treatment • Survival Analysis • Laboratory assay and vital signs • ECOG and KPS • Long term toxicity
Statistical methods:	Summary statistics were provided for all demographics, baseline, safety and tolerability variables over ITT population. Continuous demographic and baseline variables were summarized using mean, standard deviation, median, inter-quartile range, minimum and maximum. Qualitative characteristics were summarized by counts and percents. Adverse events were tabulated by intensity and summarized by system-organ class and WHO-ART term. Number of patients with at least one adverse event and dose-limiting toxicity, number of patients completing study treatment, number of patients with grade 3 neuropathy, number of patients with long-term toxicity, ECOG, and KPS were presented by counts and percents. Number of adverse events and dose-limiting toxicities occurred in patients, percent of intended dose delivered for study treatments, and delays in scheduled dosing and dose intensity were summarized by descriptive statistics such as mean, standard deviation, median, inter-quartile range, minimum, and maximum. Overall survival was evaluated by Kaplan-Meier plot. Summary statistics for laboratory evaluations at baseline and each visit were reported. All continuous variables were presented by descriptive statistics and all categorical variables were presented by frequency tables with percentage. Two interim analyses were performed on 02-Sep-2005 and 14-Jul-2006 by utilizing protocolized statistical methods

Summary:	
Efficacy/pharmacodynamic results:	N/A
Safety results:	Safety and tolerability feature of the study dosing regimen was assessed by AE incidences and toxicity evaluation. A total of 267 episodes of at least grade III adverse events/toxicities based on NCI-CTC version 2 were reported. Sixty percents of the patients experienced at least grade III pre-listed toxicities. In these, the most frequently at least grade III toxicities were classified as white cell and reticuloendothelial disorders (52.2% incidences) and as gastrointestinal disorders (11.9%) where episodes of neutrophils decreased were observed to be reported by 52.2% of the subjects and no other toxicity had more than 7.0% of incidence rate. Eleven percents of the patients were reported to suffer from other toxicities with grade III or above. In these, no episode of grade III or above in either system-organ was experienced by more than 4% of the subjects. As for the neurological toxicities, averagely 8 toxicities were experienced by each patient but less than 6.0% of the patients were reported to suffer from grade III or above toxicities. In the 159 patients, 21 (13%) experienced 25 SAEs. No episode was lethal. Most SAEs were reported as serious due to the requirement of hospitalization or prolongation of hospitalization (22 events, 88.0%). One SAE was life-threatening. A total of 19 (76.0%) were grade III or IV in severity and 10 (40.0%), 7 (28.0%), and 0 (0.0%) episodes were considered as possibly related to study medications Oxaliplatin, 5-FU, and LV, respectively. In the 21 patients with SAEs, 4 patients were reported to have allergy (19.0%), 4 were neutrophils decreased (19.0%), and 3 were ileus (14.3%). Except 2 patients were with infection, diarrhea, and fever as serious adverse events, the rest of the episodes were all singly reported. Significant adverse events were considered for episodes leading to treatment modification or permanent cessation of treatment. A total of 128 patients experienced significant adverse events, where 85 patients were considered requiring study dose modification, 97 requiring dose delay, and 40 requiring dose discontinuation, including 9 withdrawal led by adverse.events Around 82% of the patients completed all 12 cycles of study treatment and on the average, each patient were exposed to the study medication for 169 days. 1.9%, 1.3%, and 0.0% of the ITT subjects were observed of grade III neuropathy at 28-day, 6-month, and 12-month follow-up, respectively based on NCI-CTC version 2.0 (1.3%, 1.3% and 0.0% based on NCI-CTC version 1.0). Oxaliplatin, 5-FU, and LV showed good protocol compliance in median (IQR) percentage of intended dose delivered of 99.83% (0.97%), 100.0% (0.57%) and 100.0% (0.35%), respectively Two patients were known to pass away at the 12-month follow-up. The mean±SE survival time to death or last-follow up were 424.74±0.37 days. Laboratory data changes were all consistent to what have been reported in the pre-listed toxicities. All patients remained ECOG grade 0 or I after being treated with the study medication and the percentage of patients with KPS level above 80 was more than 95% for each cycle. Long-term toxicity was both singly reported at the 6-month and 12-month follow up.
Date of report:	22-Jun-2007